K013782

9.0 SUMMARY OF SAFETY AND EFFECTIVENESS

NOV 2 0 2001

"510(k) SUMMARY"

Trade/Proprietary Name:	Disetronic Penfine® Insulin Injection Pen Needle
Common/Usual Name:	Insulin Injection Pen Needle
Classification Name:	Hypodermic Single Lumen Needle

Comparison to Currently Marketed Devices
The Disetronic Penfine® Insulin Injection Pen Needles are substantially equivalent to the current Disetronic Penfine® Injection Pen Needles (K982399, K994197, K992399).

Device Description
The Disetronic Penfine® Insulin Injection Pen Needles are the same sterile, non-pyrogenic, single use needles designed to be used with commercially available Injection Pens as the 6, 8, 10 and 12 mm Disetronic Penfine® Injection Pen Needles.

Indications for Use
The Disetronic Penfine® Insulin Injection Pen Needles are intended for the hypodermic injection of insulin into the body when attached to an injector pen.

Technological Characteristics
The technological characteristics are the same as the predicate devices.

Performance Data
Performance data has been generated in compliance with existing international standards and protocols and found equivalent to the predicate devices.

Conclusion
Based on the design equivalency and the functional and safety testing, Disetronic Medical Systems has determined that the Penfine® Insulin Injection Pen Needles are substantially equivalent to the devices currently marketed in the United States.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 0 2001

Mr. David E. Chadwick
Director, Regulatory Affairs/Quality Assurance
Disetronic Medical Systems
5151 Program Avenue
Saint Paul, Minnesota 55112-1014

Re: K013782
Trade/Device Name: Disetronic Penfine Insulin Injection Pen Needle
Regulation Number: 880.5570
Regulation Name: Insulin Injection Pen Needle
Regulatory Class: II
Product Code: FMI
Dated: November 12, 2001
Received: November 14, 2001

Dear Mr. Chadwick:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K013782

NOV 2 0 2001

INDICATIONS FOR USE STATEMENT

510(k) File Number:

Device Name: Disetronic Penfine® Insulin Injection Pen Needle

Indications For Use: The Disetronic Penfine® Insulin Injection Pen Needles are intended for the hypodermic injection of insulin into the body when attached to an injector pen.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K013782

Prescription Use _____ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)